

REMARKS

The Applicants kindly acknowledge the removal of several rejections from the previous Office Action. Claims 40-42, and 50-60 are currently pending to which the Examiner has presented two rejections that are addressed in the following order:

- I. Claims 40-42 and 50-56 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cohen et al., *Neurophyschopharm* 8:365-370 (1993).
- II. Claim 40 is provisionally rejected on the alleged ground of non-statutory obviousness type double patenting over Claim 49 of co-pending application 10/193,735.

I. The Claims Are Not Anticipated

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion is not met with the Cohen et al. reference.

The Examiner argues that the Applicants' previous response to this reference was not persuasive. The Applicants' disagree for the following reasons. First, the Examiner has not recognized that the Applicants' multivariate outcome measurements comprise univariate Z scores. As previously argued, univariate Z scores are not taught in Cohen et al.¹ For this reason alone, the Examiner is respectfully requested to withdraw the present rejection.

Further, the Applicants point out that Cohen et al. does not teach a method directed to determining drug efficacy. On the contrary, Cohen et al. admits that the administered drug (i.e., ethanol); i) results in minimal blood levels:

... the small amount of ethanol ingested did not produce a measurable blood-alcohol level ...

Cohen et al., pg 367 lhc, 1 para, 2nd last sentence, and ii) is not dose related:

¹ Notably, the Examiner remained silent regarding this claim element and did not provide a rebuttal argument in the pending Office Action.

The ethanol-induced increases in SA activity did not correspond to changing blood-alcohol levels ... there were no differences between the effects of the two doses.

Cohen et al., pg 369 lhc, 1st full para. Consequently, Cohen et al. is not a proper reference for teaching a method to determine drug efficacy.

Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 40, 42, 54, and 56 to clarify that a "drug" refers to "a medication" having the following exemplary support:

Quantified neurophysiologic information distinguishes medication effects on brain function. Medications produce differential changes in the quantified neurophysiologic information that are measurable across physiologic brain imbalances, defined as psychiatric or neurological syndromes.

Applicants' Specification, pg. 10, ln 3-6 [emphasis added]. Further, the Applicants define the term "medication":

"Medications" include prescription drugs, over the counter sleeping pills, pain medication, nutritional health supplements, and megavitamins.

Applicants' Specification, pg. ln. Clearly, the Applicants' use of the term "medication" does not include any alcohols, specifically "ethanol". This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants respectfully request that the Examiner withdraw the present rejection.

II. Claim 40 Is Not Double Patented

The Examiner has reasserted the provisional rejection of withdrawn Claim 40 based upon a potential non-statutory obviousness type double patenting (35 USC § 102(E)/103(c)) over Claim 49 of co-pending application 10/193,735. The Applicants disagree and point out that the '735 application issued on February 13, 2007 as United States Patent No. 7,177,675. Consequently, the Examiner's "provisional rejection" is now moot because Claim 49 did not issue within the '675 patent. The Applicants have attached the Front Page and Claims section of the '675 to the instant response for the Examiner's convenience.

The Applicants' respectfully request that the Examiner withdraw the present double patenting rejection.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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